RVD2008-09

Re-evaluation Decision

Napropamide

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Overview

Re-evaluation Decision

After a re-evaluation of the herbicide napropamide, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration for the sale and use in Canada of products containing napropamide.

An evaluation of available scientific information found that products containing napropamide do not present unacceptable risks to human health or the environment when used according to revised label directions. As a condition of the continued registration of napropamide uses, new risk-reduction measures must be included on the labels of all products.

The regulatory approach for the re-evaluation of napropamide was first presented in Proposed Re-evaluation Document PRVD2007-06, *Re-evaluation of Napropamide*, a consultation document.[1] This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of napropamide as well as summarizes the Agency's decision and the reasons for it. Appendix I summarizes the comments received during the consultation process and provides the PMRA's response to these comments. This decision is consistent with the proposed re-evaluation decision stated in PRVD2007-06. To comply with this decision, registrants of products containing napropamide will be informed of the specific requirements affecting their product registrations and of regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Napropamide, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically, United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA is taking a regulatory decision and is requiring appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy (TSMP)).

The USEPA re-evaluated napropamide and published its conclusions in a 2005 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation section of the related Proposed Re-evaluation Decision, PRVD2007-06, *Proposed Re-evaluation Decision, Napropamide*.

What Is Napropamide?

Napropamide is a herbicide that is used to control weeds in fruit and vegetable crops, field-grown tobacco as well as ornamentals (field-grown, container-grown, ground cover, flower beds, container plantings as well as highway, industrial and foundation plantings). Napropamide is applied using a variety of ground equipment by farm workers and professional applicators. Homeowners can apply napropamide using a shaker can or granular herbicide applicator. Appendix II lists all products containing napropamide that are registered under the authority of the *Pest Control Products Act*.

Health Considerations

Can Approved Uses of Napropamide Affect Human Health?

Napropamide is unlikely to affect your health when used according to revised label directions.

People could be exposed to napropamide through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that napropamide was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Napropamide is currently registered in Canada for use on apples, grapes, peaches, pears, highbush blueberries, lowbush blueberries, strawberries, apricots, cherries, plums, asparagus, basil, cabbage, broccoli, cauliflower, Brussels sprouts, seeded Chinese broccoli, Chinese mustard cabbage, Chinese radish, seeded and transplanted Chinese cabbage (nappa), transplanted kohlrabi, squash, fuzzy squash, garlic, peppers, pumpkin, tomatoes, rutabagas, cranberries, filbert, walnut and caneberries (blackberries, boysenberries, loganberries, raspberries), and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for napropamide in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Napropamide Is Introduced Into the Environment?

Napropamide is unlikely to affect non-target organisms when used according to revised label directions.

Non-target organisms (e.g. birds, mammals, insects, aquatic organisms and terrestrial plants) could be exposed to napropamide in the environment. Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of napropamide was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions were considered to be applicable to the Canadian situation, and equivalent risk-reduction measures are currently in place in Canada. Furthermore, the PMRA will require aquatic and terrestrial buffer zones for the dry flowable formulation of napropamide to protect aquatic organisms and terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of napropamide, the PMRA is proposing further risk-reduction measures for commercial product labels.

Human Health

- To protect mixers/loaders/applicators: additional protective equipment
- To protect workers re-entering treated sites: a restricted-entry interval

Environment

- To protect non-target sensitive aquatic organisms and terrestrial plants: buffer zones for aquatic and terrestrial habitats

Appendix III lists all required label amendments, including instructions related to basic hygiene practices.

Other Information

Any person may file a notice of objection[3] regarding this decision on napropamide within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1.0 Comment on proposed buffer zone requirements

The proposed buffer zones for the protection of sensitive terrestrial habitat range from 10 to 40 metres. This could leave large untreated strips in fields, which could act as a weed bank and increase problems with weed management in the remainder of the field.

Response

It should be recognized that buffer zones are required only if sensitive habitats are downwind from the point of application. Buffer zones are not required when sensitive habitats are upwind from the application area and, if necessary, a previously unsprayed area could be sprayed at another time under favourable meteorological conditions.

In addition, the PMRA has released Regulatory Proposal PRO2005-06, *Agricultural Buffer Zone Strategy Proposal*, for stakeholder comment. The document outlines buffer zone reduction strategies based on meteorological and equipment factors. The PMRA is currently working on finalizing this policy.

2.0 Comment on windbreaks

Windbreaks are often located within a 5-metre distance from the edge of a crop. Many growers have planted windbreaks to help reduce soil erosion and wind damage to crops, improve pesticide applications by reducing wind speed, and to catch drifting pesticides. Although contact with drift from napropamide applications may be injurious to windbreaks and should be avoided, if windbreaks were included in the definition for sensitive terrestrial habitats, that would contradict the use of windbreaks and discourage new plantings of windbreaks. This issue may be better addressed with a label statement alerting pesticide applicators that napropamide may be injurious to sensitive terrestrial habitats, including windbreaks, and should be avoided.

Response

The PMRA recognizes that windbreaks, or shelterbelts, are often planted by farmers to improve agricultural conditions and minimize off-target spray drift. However, under current PMRA policy, these areas are included in the definition for sensitive terrestrial habitats because of their valuable role in providing food and shelter for a wide range of animals. The PMRA does not put statements on labels recommending that "spray drift to sensitive terrestrial habitats should be avoided" because they are not legally enforceable and do not provide the applicator with information on conditions under which damage could occur.

The PMRA is committed to examining ways of promoting land stewardship practices in the agricultural sector and does not want to discourage farmers from planting these valuable windbreaks. In 2008 the PMRA will be reviewing its habitat protection goals and will undertake a focussed consultation session with the scientific community to better define habitat requirements for maintaining ecological function. It is also hoped that the finalization of the buffer zone reduction strategy will allow applicators more flexibility in pesticide applications.

As mentioned in the response to comment 1.0 above, it should be recognized that buffer zones are required only if sensitive habitats are downwind from the point of application.

For napropamide, buffer zones may be reduced by application with drift-reducing spray shields on the spray boom. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%, which in this case means that the buffer zones would be 3 to 12 m. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%, or in this case, buffer zones would be 7 to 28 m.

Appendix II Current Canadian Registered Products Containing Napropamide as of 1 January 2008

Registrant	Registration Number	Guarantee (%)	Product Name	Formulation Type	Class
United Phosphorus Inc.	20122	94	Devrinol Technical Herbicide	Solid	Technical
United Phosphorus Inc.	25297	2	Devrinol 2-G Selective Herbicide Granular	Granular	Commercial
United Phosphorus Inc.	25230	10	Devrinol 10-G Selective Herbicide Granular	Granular	Commercial
United Phosphorus Inc.	25231	50	Devrinol 50 DF Selective Dry Flowable Herbicide	Dry flowable	Commercial
United Phosphorus Inc.	28511	2	Devrinol 2-G Manufacturing Concentrate	Granular	Manufacturing
United Phosphorus Inc.	28512	2	Devrinol 2-G Ready-to-Use Herbicide	Granular	Domestic
United Products Canada Inc.	28731	2	Granular Weed Preventer	Granular	Domestic

Appendix III Revised Label Amendments for Commercial Products Containing Napropamide

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

> Wear long pants, a long-sleeved shirt and chemical-resistant gloves during mixing/loading, clean-up and repair activities.
>
> Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours.

II) The following statement must be included in the **DIRECTIONS FOR USE** section:

> It is recommended that this product not be applied in a way that will contact workers or other persons, either directly or through drift. Only handlers wearing personal protective equipment may be in the area during application.

III) For the commercial dry flowable end-use product, Registration Number 25231, the following statement must be included in the **DIRECTIONS FOR USE** section:

> Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.
>
> **DO NOT** apply by air.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of:		
		Aquatic Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	
Field sprayer*	Fuzzy squash	1	0	10
	Basil, broccoli, Brussels sprouts, cabbage, cauliflower, Chinese broccoli, Chinese mustard cabbage, Chinese radish, Chinese cabbage, garlic, kohlrhabi, pepper, pumpkin, rutabaga, squash, strawberry, tobacco and tomato	1	0	15
	Newly planted fruit trees	2	1	25
	Established fruit trees, grapes, caneberries, lowbush and highbush blueberries, asparagus (seedlings and new plantings), and field-grown nursery and container stock	2	1	30
	Established asparagus	3	1	40

* For field sprayer application, buffer zones can be reduced with the use of drift-reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

IV) For the commercial dry flowable end-use product, Registration Number 25231, the following statement should be included in the **ENVIRONMENTAL HAZARDS** section:

TOXIC to aquatic organisms and non-target terrestrial plants. Observe buffer zones specified under **DIRECTIONS FOR USE**.

References[4]

List of Studies/Information Submitted by Registrant

PMRA 1534196 1997, NAPROPAMIDE: Preliminary Analysis, Certification of Limits, and Methods of Analysis to Verify Certified Limits for Sandbach (UK), CGR 10/97, DACO: 2.12.1,2.13.1,2.13.3

PMRA 1534195 1997, Napropamide: Product Identity, Description of Beginning Materials and Manufacturing Process and Discussion of the Formation of Impurities for Napropamide Technical (TGAI) Produced by United Phosphorus at Sandbach UK, RAD 1822, DACO: 2.11.1,2.11.2,2.

PMRA 791788 2003, DEVRINOL TECHNICAL Establishing Certified Limits Note to Reviewer, N/S, MRID: N/S, DACO: 2.12.1 CBIPMRA 7917862003, DEVRINOL TECHNICAL Manufacturing Methods for the TGAI Note to Reviewer, N/S, MRID: N/S, DACO: 2.11 CBI

PMRA 791790 2002, Preliminary Analyses of Five Representative Production Batches of Napropamide Technical Grade Active Ingredient (TGAI) to Determine % Napropamide and to Quantify its Associated Impurities, 3793, MRID: N/S, DACO: 2.13.1,2.13.2,2.13.3 CBI

[4] These references are in relation to the chemistry section of PRVD2007-06. They are included in this document because the PMRA reference numbers were not yet available at the time of publication of PRVD2007-06.